

REMARKS

I. Amendments

Reconsideration of the rejections in the Application is respectfully requested. Upon entry of the foregoing amendment, claims 1 and 84-136 will be pending. Claims 85, 88, 90, 95, and 96 are amended. New claims 111-136 are added. Claims 1 and 84-110 stand rejected.

Support for the amendments to the claims and for the new claims can be found throughout the specification (considered as a whole) and in the claims as originally filed. Claims 85, 88, 90, and 96 have been amended to put the claims in proper form. Support for further amendments to claim 88 can be found, *inter alia*, in the specification at Example 3. Support for the amendment to claim 95 can be found, *inter alia*, in the specification at page 10, lines 26-29. Support for new claims 111 and 129 can be found, *inter alia*, in claim 88 as originally filed and in the specification at page 5, lines 34-39 and Example 3. Support for new claims 112-115 can be found, *inter alia*, in claim 90 as originally filed. Support for new claims 116 and 117 can be found, *inter alia*, in claim 84 as originally filed and in the specification at page 4, lines 15-23. Support for new claim 118 can be found, *inter alia*, in the specification at page 2, lines 37-38. Support for new claims 119 and 120 can be found, *inter alia*, in the specification at page 4, lines 5-8. Support for new claims 121 and 122 can be found, *inter alia*, in the specification at page 4, lines 18-23. Support for new claims 123-128 can be found, *inter alia*, in the specification at page 5, lines 10-19. Support for new claim 130 can be found, *inter alia*, in the specification at page 12, lines 8-25. Support for new claims 131-135 can be found, *inter alia*, in the specification at page 13, lines 1-13. Support for new claim 136 can be found, *inter alia*, in the specification at page 13, lines 19-23.

Based on the above amendments and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

II. Claim Rejections Under 35 U.S.C. § 102(e)

Claims 1 and 84-110 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2002/0012982, in the name of Blakesley, *et al.* ("Blakesley"). See Office Action, p. 2. Applicants respectfully traverse this rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131 (8th ed., rev. 5) (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)).

Initially, Applicants point out that although claims 1 and 84-110 have been rejected, the Office Action only provides support for the rejection of claims 1, 84-87, and 107. Therefore, Applicants directly address only the rejections of claims 1, 84-87, and 107; however, Applicants respectfully submit that claims 88-106 and 108-110 are also not anticipated by Blakesley for the reasons set forth below.

Claim 1 of the Application recites a device for sampling or collecting comprising (i) a swab which is a natural or synthetic absorbent material comprising gelatine particles or collagen particles and (ii) a support fixed to said swab. Claim 84, from which claims 85, 87, and 107 depend, recites a device for sampling or collecting comprising (i) a swab comprising gelatine or collagen and (ii) a support attached to said swab.

Blakesley discloses compositions, methods, and kits for use in extracting and isolating protein and peptide molecules. See p. 1, ¶ [0008]. The pore-containing matrix used in the invention of Blakesley may be a solid matrix in the form of a frit, plug, cartridge, or swab tip in one embodiment of the invention or a semi-solid matrix in the form of beads or a gel supported by a solid support material in an alternative embodiment of the invention. See p. 5, ¶ [0056] and p. 9, ¶ [0087]. Blakesley does not, however, teach or suggest a swab comprising gelatine or collagen and a support attached to the swab. In fact, Blakesley explicitly states that the solid matrix, such as a swab tip, may be made from polyester, scintered polyethylene, nitrocellulose, polyolefin, cellulose acetate, nylon, cellulose, silica, and the like. See p. 9, ¶ [0087]. Thus,

Blakesley does not teach each and every element of the present invention, either explicitly or inherently.

For at least the aforementioned reasons, Applicants respectfully submit that Blakesley does not anticipate the claims of the present invention and request that the rejection be withdrawn.

III. Claim Rejections Under 35 U.S.C. § 103(a)

In *Graham v. John Deere*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966), the Supreme Court set out a fact-based three prong test for considering and determining obviousness under 35 U.S.C. § 103. The three prong analysis is as follows: 1) determine the scope and contents of the prior art; 2) ascertain the differences between the prior art and the claims in issue; and 3) resolve the level of ordinary skill in the pertinent art. See M.P.E.P. § 2141(I).

In addition, the legal determination of obviousness dictates that the examiner bears the initial burden of establishing a *prima facie* case of obviousness. If the examiner does not satisfy his/her burden, then the applicant (in this case, Patent Owner) is not obligated to submit evidence of nonobviousness. See M.P.E.P. § 2142.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

M.P.E.P. § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed Cir. 1991)).

A. Blakesley

Claims 108 and 109 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Blakesley. See Office Action, p. 3. Applicants respectfully traverse this rejection.

The Office Action asserts:

Blakesley does not teach a mammalian or specifically a marine mammalian gelatine source, however the swab taught by Blakesley with a gelatine sponge from a marine mammalian gelatine source would be a swab which is substantially identical to the agarose gel swab taught by Blakesley, therefore it would be obvious to one of ordinary skill in the art to substitute a marine mammalian gel sponge for the agarose sponge taught by Blakesley with a reasonable expectation of success.

P. 3.

The Office Action, however, misconstrues the disclosure of Blakesley. As described above, the swab tip is the solid lysis/filter matrix used to isolate protein or

peptide molecules in one embodiment of the invention disclosed in Blakesley. See p. 9, pars. [0080]-[0087]. Agarose may be used as material for a gel matrix (see p. 3, par. [0030], but, the gel matrix is a semi-solid matrix used in a different embodiment of the invention disclosed in Blakesley. See p. 5, par. [0056]. This is further illustrated by the fact that "gels" and "swab tip" are listed separately as different forms of the matrix. See p. 3, par. [0030]. Blakesley does not teach or suggest that a swab itself may comprise gel, as claimed in the present invention. Therefore, Blakesley differs significantly from the claimed invention.

The claimed invention also is not *prima facie* obvious over Blakesley. First, because Blakesley does not teach or suggest that a swab comprises gelatine or collagen, Blakesley also does not suggest or motivate one of ordinary skill in the art to modify the disclosure of Blakesley to create a swab comprised of gelatine or collagen originating from a mammal, and more particularly, a marine mammal.

Moreover, the present invention is a device used for sampling or collecting, for example, for the presence of microorganisms and optionally to cultivate the microorganisms (see specification, p. 6, ll. 35-39) whereas the swab in Blakesley is used to lyse cells. One of ordinary skill in the art would not use the same material that was used to lyse cells to sample for microorganisms, which must remain intact for cultivation. The invention disclosed in Blakesley is nonanalogous to the art of the present invention. M.P.E.P. § 2141.01(a)(I) states, "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned" (quoting *In re Oetiker*, 977 F.2d 1443, 1446, 24 U.S.P.Q.2d 1443, 1445 (Fed. Cir. 1992)). Blakesley is neither in the field of applicant's endeavor nor pertinent to the particular problem of concern in the present invention.

Second, one of ordinary skill in the art would also not have a reasonable expectation of successfully reaching the claims of the present invention from the disclosure of Blakesley. As previously discussed, Blakesley is trying to lyse cells whereas the present invention may be used to collect intact microorganisms for cultivation. Thus, one of ordinary skill in the art would not have a reasonable

expectation to adapt the solid swab lysis matrix of Blakesley to obtain the swab comprising gelatine or collagen of the present invention.

Finally, Blakesley falls woefully short of teaching or suggesting all of the claim limitations of the present invention. As described in Section I above, Blakesley does not teach or suggest a device for sampling or collecting comprising (i) a swab comprising gelatine or collagen and (ii) a support attached to said swab, much less that the gelatine or collagen originate from a mammal, particularly a marine mammal.

For at least the foregoing reasons, Applicants respectfully submit that the present invention is patentable over Blakesley and request that the rejection be withdrawn.

B. Blakesley in View of Ashton

Claims 88 and 90 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Blakesley in view of U.S. Patent No. 5,387,208, issued to Ashton, *et al.* ("Ashton"). See Office Action, p. 3-4. Applicants respectfully traverse this rejection.

As described in Section II(A) above, Blakesley does not render the present invention obvious. The disclosure of Ashton does not supplement the inadequacies of Blakesley. First, one of ordinary skill in the art would not use the absorbent gel of Ashton for the gel lysis/filter matrix of Blakesley because the sample would be absorbed instead of passing through the gel and lysing the cells in the sample. Therefore, one of ordinary skill in the art would not be motivated to combine the disclosures of Blakesley and Ashton.

Furthermore, as previously pointed out, Blakesley is nonanalogous to the art of the present invention. Ashton, which discloses absorbent articles such as diapers, incontinent briefs and undergarments, training pants, and feminine hygiene products (see col. 5, ll. 24-35), is nonanalogous to both the art described in Blakesley and the present invention because it is not in the field of Blakesley's or applicant's endeavor nor is it pertinent to the particular problem of concern in Blakesley or the present invention. See M.P.E.P. § 2141.01(a)(I).

Second, even if one of ordinary skill in the art did combine the disclosures of Blakesley and Ashton, he/she would not have a reasonable expectation of successfully obtaining the claimed invention. Blakesley describes a semi-solid gel matrix that is separate and apart from a solid swab matrix. Ashton does not describe a swab; Ashton

describes an absorbent gel. See col. 10, ll. 21-28. Therefore, the combination does not suggest teach a device for sampling or collecting comprising a gelatine-based sponge swab and a support attached to said swab, wherein the swab has a water absorption capacity of at least 30 g/g or wherein the swab is made of a natural or synthetic absorbent material comprising gelatine particles or collagen particles having a particle size in the range of about 1 μ m to about 1 mm. Similarly, the combination of Blakesley and Ashton would fall short of teaching or suggesting each limitation of the claimed invention.

For at least the foregoing reasons, Applicants respectfully submit that the present invention is patentable over Blakesley in view of Ashton and request that the rejection be withdrawn.

Although the Office Action only rejects claims 88 and 90 as being unpatentable over Blakesley in view of Ashton, the Office Action makes reference to claims 89 and 91-95. Even if claims 89 and 91-95 are also rejected, Applicants respectfully submit that claims 89 and 91-95 are also patentable over Blakesley in view of Ashton for the aforementioned reasons.

CONCLUSION

All of the stated grounds of rejection have been properly traversed. Applicants, therefore, respectfully request that the Examiner reconsider all presently outstanding rejections and that the rejections be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

The Examiner is respectfully requested to contact the undersigned by telephone at the below listed telephone number in order to expedite resolution of any issues and to expedite passage of the present application to issue if any comments, questions, or suggestions arise in connection with the present application.

It is believed that no additional fees are due in connection with this Response. However, if the USPTO determines that a variance exists in the amount due and the amount authorized above, the Commissioner is hereby authorized to credit or debit any such variance to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS LLP

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By:



Robin L. Teskin
Registration No. 35,030

Victoria A. Silcott
Registration No. 57,443

HUNTON & WILLIAMS LLP
1900 K Street, N.W.
Suite 1200
Washington, D.C. 20006-1109
Telephone: (202) 955-1500
Facsimile: (202) 778-2201